

REMARKS

By the present amendment, Claims 151-157, 159-170 and 174-210 are cancelled without prejudice or disclaimer, and Claims 219-272 are added and presently pending. No fees for claims are believed due. If any additional fee is deemed payable, please charge such a fee (or credit any overpayment) to Deposit Account No. 13-0019.

The amendments made herein focus the presently claimed invention on certain embodiments. No new matter is added by this amendment. Support for the new claims can be found throughout the specification and claims as filed. Exemplary support for each new claim is provided in the table below.

Claim No.	Exemplary Support
Claim 219	p. 15, ll. 12-14; p. 20, l. 16 to p. 21, l. 12; p. 21, ll. 20-22; p. 21, l. 27 to p. 22, l. 15; p. 22, ll. 18-27; p. 23, ll. 5-8; p. 25, l. 25 to p. 26, l. 7; p. 30, l. 25 to p. 31, l. 7; p. 31, ll. 8-14; p. 40, l. 15 to p. 46, l. 15; p. 95, ll. 5-8; Table 9 pp. 98-99
Claim 220	p. 25, ll. 7-10; p. 111, ll. 10-21
Claim 221	p. 25, ll. 7-10; p. 18, ll. 12-17; p. 111, ll. 10-21
Claim 222	p. 37, ll. 24-25
Claim 223	p. 25, ll. 25-27
Claim 224	p. 25, l. 25 to p. 26, l. 7
Claim 225	p. 41, ll. 11-12
Claim 226	p. 24, l. 7 to p. 25, l. 6
Claim 227	p. 24, l. 7 to p. 25, l. 6
Claim 228	p. 24, l. 27; p. 24, l. 22
Claim 229	p. 24, ll. 25-27
Claim 230	p. 40, ll. 16-20
Claim 231	p. 40, l. 18
Claim 232	p. 44, ll. 16-17
Claim 233	p. 40, l. 18
Claim 234	p. 31, ll. 10-14
Claim 235	p. 31, ll. 10-14
Claim 236	p. 20, l. 16 to p. 21, l. 12
Claim 237	p. 20, l. 16 to p. 21, l. 12

Claim No.	Exemplary Support
Claim 238	p. 20, l. 16 to p. 21, l. 12
Claim 239	p. 42, ll. 22-23
Claim 240	p. 42, ll. 22-23
Claim 241	p. 22, ll. 11-13
Claim 242	p. 23, l. 13
Claim 243	p. 22, ll. 13-14
Claim 244	p. 22, l. 14
Claim 245	p. 44, ll. 7-14
Claim 246	p. 22, ll. 18-27
Claim 247	p. 130, ll. 10-15
Claim 248	Table 9-12, Patients 2, 6, 7, 11, 13, 15, 17
Claim 249	p. 28, l. 25 to p. 29, l. 6
Claim 250	p. 19, ll. 21-23
Claim 251	p. 7, ll. 10-12; p. 13, ll. 23-25; p. 15, ll. 12-14; p. 18, ll. 12-17; p. 20, l. 16 to p. 21, l. 12; p. 21, ll. 20-22; p. 21, l. 27 to p. 22, l. 15; p. 22, ll. 18-27; p. 23, ll. 5-8; p. 25, ll. 7-10; p. 25, l. 25 to p. 26, l. 7; p. 30, l. 25 to p. 31, l. 7; p. 31, ll. 8-14; p. 40, l. 15 to p. 46, l. 15; p. 57, ll. 22-24; p. 87, l. 18; p. 95, ll. 5-8; p. 111, ll. 10-21; Table 9 pp. 98-99
Claim 252	p. 31, ll. 10-14
Claim 253	p. 31, ll. 10-14
Claim 254	p. 20, l. 16 to p. 21, l. 12

Claim No.	Exemplary Support
Claim 255	p. 20, l. 16 to p. 21, l. 12
Claim 256	p. 20, l. 16 to p. 21, l. 12
Claim 257	p. 42, ll. 22-23
Claim 258	p. 22, ll. 11-13
Claim 259	p. 22, l. 13
Claim 260	p. 24, l. 7 to p. 25, l. 6
Claim 261	p. 37, ll. 24-25
Claim 262	p. 25, ll. 25-27
Claim 263	p. 25, l. 25 to p. 26, l. 7

Claim No.	Exemplary Support
Claim 264	p. 24, l. 7 to p. 25, l. 6
Claim 265	p. 44, ll. 7-14
Claim 266	p. 40, ll. 16-20
Claim 267	p. 40, l. 18
Claim 268	p. 40, l. 18
Claim 269	p. 44, ll. 16-17
Claim 270	p. 130, ll. 10-15
Claim 271	p. 28, l. 25 to p. 29, l. 6
Claim 272	p. 19, ll. 21-23

RESPONSE TO OFFICE ACTION DATED MAY 2, 2006

1. The Rejection Under 35 U.S.C. § 112 Should Be Withdrawn

Claims 151-157, 159-170 and 174-210 were rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement requirement. Applicant respectfully traverses this rejection.

“The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.” *United States v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988). Routine experimentation does not constitute undue experimentation. *Johns Hopkins University v. Cellpro, Inc.*, 152 F.3d 1342 (Fed. Cir. 1998).

Upon reading the specification of the pending application, one of skill in the art at the time of the invention would have been able to prepare numerous compositions that would fall within the scope of the pending claims. In addition, this skilled artisan would have been able to determine the blood concentration level of the proton pump inhibitor to ascertain whether, after the administration of the composition, a blood serum concentration falling within the scope of the claims was reached. This type of routine testing would not constitute “undue experimentation” and, therefore, withdrawal of this rejection is respectfully requested.

Moreover, Applicant notes that the independent claims now pending do not recite the language rejected in the Office Action and, therefore, this rejection is moot with respect to these claims.

2. Obviousness-Type Double Patenting

Claims 151-157, 159-170 and 174-210 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims issued in U.S. Patent Nos. 6,699,885; 6,645,988; 6,489,346; and 5,840,737.

Applicant respectfully disagrees with the Examiner's position that Horowitz demonstrates the "innate nature" of the plasma concentration 30 minutes after administration of the invention claimed in each of these patents. As just one example, Horowitz is inadequate to show the "innate nature" of at least some of the issued claims because the method described in Horowitz employs about 3,700 mg of sodium bicarbonate per 90 mg of omeprazole—an amount of buffer that could not practically be used in a solid oral dosage form. Yet, many of the claims in the patents cited by the Examiner are specifically directed to solid oral dosage forms. As a second example, Horowitz discloses the administration of 300 ml of a 160 mmol/l of sodium bicarbonate solution (about 48 mEq of sodium bicarbonate) in divided doses, before, together with and for 30 minutes after administration of uncoated omeprazole. There is simply no evidence in Horowitz suggesting that the claimed pharmacokinetic profile would naturally result if any one of the parameters around the administration step in Horowitz were changed. Thus, Applicant respectfully asserts that the Examiner's basis for this rejection is improper.

Nevertheless, Applicant will submit a terminal disclaimer upon the indication of allowable subject matter.

3. The Rejection Under 35 U.S.C. § 102(b) and 35 U.S.C. § 103 Should Be Withdrawn

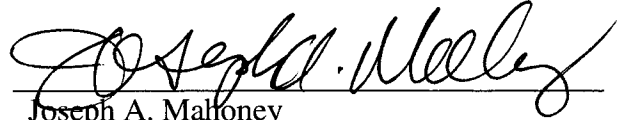
Claims 151-157, 159-170 and 174-210 stand rejected under 35 U.S.C. §§ 102(b) and 103 as being anticipated by or obvious in view of Carroll *et al.* ("Carroll"), McCullough U.S. Patent No. 5,447,918 ("McCullough"), Depui *et al.* WO 97/25066 ("Depui"), JP 05-255088 ("JP-088") as supplemented with Horowitz. Applicants respectfully traverse this rejection insofar as it was applied to the previously pending claims.

The claims now pending are directed to solid oral dosage forms and require a specific T_{\max} of the proton pump inhibitor. Because these limitations were not present in the previously pending claims, the Examiner's rejections are not applicable and withdrawal of the rejection is respectfully requested.

Conclusion

All claims presented herein are believed to be in condition for allowance. Early and favorable consideration of this application is respectfully requested. Kindly contact the undersigned with any questions or to otherwise expedite prosecution.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Joseph A. Malloney", written over a horizontal line.

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